



Plant Systems Audit Report

Date of Audit: May 01,2005

Facility Name: XYZ Company

Plant Address:

City:

State:

Zip:

Country: USA

Telephone:

Fax:

Mailing Address:

Address: Same as Above

City:

State:

Zip:

Contact Person for USDA:

Name:

Title:

Evaluation Elements	Facility Score	Percentage of Available Points Score	Minimum Points Required 1/	Possible Points
I. Food Safety	300	100%	270	300
II. Quality Management Systems	80	100%	64	80
III. Personnel	125	100%	100	125
IV. GMPs/Sanitation	275	100%	220	275
V. Pest Control	50	100%	40	50
VI. Packaging/Labeling/Warehousing	100	100%	80	100
VII. Recall/Return	70	100%	56	70
VIII. Food Defense	80	100%	64	80
Scoring System		Audit Results Summary		
98.5% to 100% = Superior 95.0% to 98.4% = Excellent 87.5% to 94.9% = Acceptable Less than 87.5% = Unacceptable 1/ Facility must meet the minimum points required for each section.		Facility Score (total points): 1080 Facility Score (percent): 100.0% Facility Rating : Superior		
If Unacceptable, account:				

Auditor: Area Office: Washington, DC Phone: 202-720-5021

Auditor's Signature: _____

Supplier: XYZ Company, ,
Audit Date: 05/02/2005

Products packed:

Summary of Deficiencies:

Observations/Improvements:

I. Food Safety

A. Internal Quality Audit

1.*	0	Are there procedures in place for management/supervisors to conduct internal reviews of Quality Systems?
2.	0	Are Internal audit findings documented and reported to upper management?
3.*	0	Are Corrective Action Reports followed up and documented to determine effectiveness?

B. Purchasing

4.	0	Is there a system in place to evaluate and approve suppliers?
5.	0	Are suppliers evaluated for good agricultural practices? (i.e. Do they have process controls in place covering pesticide control, harvesting, and transportation practices?)
6.	0	Are purchasing documentation/records, including Certificates of Conformance (COC) and Certificates of Analysis (COA), maintained, current, and applicable?
7.*	0	Are receipt inspections performed and documented on incoming product (Product condition, accuracy of invoice, product identity, etc.)? Is there documentation of the disposition of rejected product?
8.*	0	Are acceptance criteria documented for incoming ingredients? Do these procedures include testing for quality, foreign material, pesticides, and/or microbial contamination?
9.	0	Is domestic origin compliance verified? (i.e., product can be traced to US origins) (where required by contract)

C. Process Control (see attached for appropriate commodity)

10.	0	Is there a system in place for the proper handling, segregation, and storage of raw materials?
11.	0	Are raw materials washed or cleaned as necessary to remove soil or other contamination?
12.*	0	If water is part of the finished product, is there a drinking water quality analysis available? (chemical analysis)?
13.*	0	Is the processing/ingredient water potability certificate available? Date of certificate:
14.*	0	Is forced air that is used on product or food contact surfaces free from contaminations?
15.1/	0	Microbiological testing includes: 0 Tests required by specification or contract: 0 Routine analysis of food contact surfaces: 0 Environmental testing program (floors, walls, ceilings, etc.): 0 Testing of finished product:
16.	0	Is there a documented empty package integrity testing program? (e.g., can, mylar bags, paper sacks, etc.)
17.*	0	Are procedures in place to prevent shipment/use of non-conforming raw materials or finished product?
18.	0	Are ingredients properly weighed out and pre-blended according to the formula or specification?
19.*	0	Are sensitive ingredients maintained at the correct temperature during staging?
20.	0	Is product handled in manner designed to preclude contamination?

21.	0	Are in-process thermometers, timers, etc. properly calibrated according to a defined schedule and are results documented?
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D. Foreign Material Contamination Prevention (Complete 1. and/or 2., as appropriate)

1. Metal Detection

22.*	0	Is calibration performed with ferrous, non-ferrous, and stainless steel standards? Verification?
23.*	0	Is there adequate documentation of metal detector's operation?
24.*	0	Is there an automatic rejection system in place and is it functioning properly?
25.*	0	Is there a written action plan in place for when test or metal detector fails?

2. In-line Magnet Traps, In-line Screen, Line filters, Blower or Rock Traps

26.*	0	Are there an adequate number/location of magnets/screens/filters? Is the frequency of inspection of the magnets/screens/filters adequate? Are the results of every magnet/screen/filter inspection documented?
27.*	0	Does a written action plan exist for when integrity of magnets/screens/filters has been compromised?

3. Extraneous Physical Hazard Prevention Program

28.*	0	Are light bulbs protected?
29.*	0	Is there a glass container accounting system in place?
30.*	0	Are can cleaners (steam, air or water) located on each line for glass, tin or semirigid containers?
31.	0	Is facility free from peeling paint, rust, loose nuts and bolts?

E. Allergen Controls

32.	0	Are there procedures in place for management to identify all allergenic materials (eight major allergens are peanuts, tree nuts, eggs or egg products, milk or dairy products, crustaceans, fin fish, soy and wheat; chemical sensitivities are sulfites and/or food colorings) present in the facility? What are the allergens that have been identified?
33.	0	Are raw material supplies organized in such a way to prevent cross-contamination of products? Are these procedures applied to product being processed and to stored finished product? (Physical segregation/labeling)
34.	0	Are production schedules planned to eliminate possible cross-contamination?
35.	0	Do sanitation procedures address the issue of possible cross-contamination between products? Is allergen cleaning verified? (All allergens cleaned from processing surfaces, etc.)
36.	0	Is allergen control a part of the company's training program with all employees (including new employees and on an annual basis)?
37.	0	Is the presence of an allergen clearly stated on finished product labels in terms understandable by the consumer? Does the firm include warning statements (for example, "May contain peanuts" or "Produced in a facility where peanuts are processed") on product labels when appropriate?
38.	0	Does the company's internal audit system include a review of their allergen control procedures?

Process Control: Canned Fruits and Vegetables**Addendum Sheet**

A1.	0	Are processing schedules for thermal processed products on file and available for review?
A2.	0	Are processing parameters posted on cooker panel or in cook room?
A3.*	0	Does the process schedule include (as appropriate): Container dimensions Minimum product initial temperature (IT) Minimum process time and temperature Critical factors (fill weight, maximum pH, etc.) Minimum F-value delivered by the process
A4.	0	Are the critical factors measured and documented during processing?
A5.	0	Are retort records complete and accurate (retort operation/continuous cooker checklist, temperature record chart)?
A6.	0	Is the product cooled in accordance with specifications before packaging?
A7.*	0	If process deviations occur: Is the deviation satisfactorily addressed? Did the proper documentation take place? Is there a process deviation logbook for the last three years, previous to the current year?
A8.*	0	Is double seam tear down performed in accordance with Good Manufacturing Practices (at least every four hours)? Were results documented? Were the can manufacturer's guidelines met? Are visual double seam exams completed within current guidelines (1-container/closing machine/closing head/30 minutes)? Were results documented? Does the company recycle water? Are water chlorinating records accurate and complete? How often is the water checked for sanitizer levels?
A9.	0	Does each retort have at least one calibrated mercury-in-glass (MIG) thermometer, one temperature control device, and one temperature recording device? Are the MIG thermometers calibrated annually against a certified thermometer?
A10.	0	Are low acid or acidified products produced? If so, does the supervisor for each shift of operation hold a Better Process Control certification? Does a certified person sign the process records within a 24-hour time frame?
A11.	0	Are low acid products produced? If so, are process records routinely reviewed by any authority (i.e. State or FDA)? Date of last regulatory visit:
A12.	0	Do "hot fill and hold" products meet time and temperature parameters?

Process Control: Frozen Fruits and Vegetables**Addendum Sheet**

A1.*	0	If heat blanching is used, is the product held at the required temperature for an adequate time?
A2.	0	Is there a documented procedure in place for the periodic cleaning of the blancher?
A3.*	0	Do microbiological results show micro levels in control?

A4.*	0	Are the free chlorine levels in the cooling water in control?
A5.*	0	Do non-blanching products go through a sanitizing step?
A6.*	0	Is the finished product maintained at a suitable temperature?

Process Control: Dairy Products

Addendum Sheet

A1.*	0	Are raw product storage temperatures adequate? Are temperatures recorded?
A2.	0	Are products pasteurized or heat treated and stored as per appropriate Standards of Identity?
A3.	0	Are pasteurization units properly timed and sealed? Documentation of State reports available?
A4.	0	Are pasteurization charts properly identified and marked?
A5.	0	Are finished product temperatures adequate? Are temperatures recorded?
A6.	0	Are raw and finished product processed properly segregated?
A7.	0	Are product streams properly protected?
A8.	0	Do any cross connections exist?

Process Control: Grain Milling

Addendum Sheet

A1.*	0	Incoming grain inspected for aflatoxin, quality, and infestation?
A2.*	0	Granulation routinely tested to ensure proper milling?
A3.*	0	Proper handling and disposal of grain spills and leaks?
A4.	0	Plant operations conducted in manner designed to minimize potential for explosions, fires, or excessive dust accumulation?
A5.	0	Vitamin and mineral premix added according to specification?
A6.*	0	Process design precludes cross contamination of product streams (especially those designated as animal feed and human consumption).

Process Control: Dried Fruits & Vegetables

Addendum Sheet

A1.*	0	Is the sulfuring or other preserving process with good commercial practice?
A2.*	0	Do microbiological results show micro levels in control?
A3.*	0	Are the moisture levels or water activity levels evaluated and recorded?
A4.*	0	Do the products go through a sanitizing step?
A5.*	0	Does the process address storage temperature of the finished product? Is it being followed?

Process Control: Seafood

Addendum Sheet

A1.**	0	Has a Hazard Analysis been performed at this facility?
A2.	0	Is there a written HACCP plan? <input type="checkbox"/> Yes <input type="checkbox"/> No If so, has it been implemented?
A3.	0	Is the HACCP plan location and/or species specific?

A4.	0	Are all food safety hazards listed in the plan?
A5.**	0	Are controls in place for the identified food safety hazards?
A6.	0	Does the HACCP plan list critical control points (CCP) for each of the identified food safety hazards?
A7.	0	Does the HACCP plan list the critical limits that must be met at each of the CCPs?
A8.	0	Are the critical limits followed?
A9.	0	Are the monitoring procedures in the HACCP plan adequate?
A10.	0	Are the monitoring procedures being followed?
A11.	0	Is the corrective action listed in the HACCP plan appropriate?
A12.**	0	Did the processor take corrective action when a deficiency was found?
A13.	0	Are the verification procedures stated in the HACCP plan adequate?
A14.**	0	Are the verification procedures being followed?
A15.	0	Are there documented sanitation standard operating procedures present, specific for each production area?
A16.	0	Is sanitation monitored throughout the facility to ensure compliance with GMPs? (21 CFR Part 110)
A17.	0	Are the sanitation standard operating procedures being followed?
A18.	0	Has the processor established and implemented a defect action plan/quality manual? <input type="checkbox"/> Yes <input type="checkbox"/> No If so, is it being followed?

** Critical HACCP/safety issue -- Deficiency results in Unacceptable audit rating.

Minimally Processed Fresh Fruits & Vegetables Sheet

Addendum

A1.*	0	Are suppliers required to provide a written guarantee, or other documentation, stating that they have addressed good agricultural practices, such as: a. General condition and history of use of supplier's fields (and fields/areas adjacent to the supplier's fields) appropriate for present use; b. Type of water used for irrigation/pesticide application is appropriate; c. If manure is used as fertilizer, that it has been properly composted and applied; d. Sanitary facilities in field (toilets, handwashing facility), working conditions, and harvesting equipment promote proper handling of produce; e. Handling practices that minimize drift from adjacent fields, manure piles, or storage areas, and that prevent contamination from uncontrolled animal feces. Does the company visit any of the suppliers' fields to verify good agricultural practices?
A2.*	0	Are suppliers required to provide a written guarantee, or other documentation, stating that pesticide application and type of pesticide used is in accordance with all County, State, and Federal Laws and Regulations?
A3.*	0	If the water used in the facility is recirculated or reused, does the water flow counter to the movement of the produce through the facility? Is chlorine, or another antimicrobial agent, added to the wash water?
A4.*	0	During hydro-cooling, do procedures prevent microbial cross contamination between containers due to dripping water/coolant?

A5.*	0	Are bins/containers reused? If so, are there provisions in place to ensure that the food contact surfaces are maintained in clean and sanitary condition?
A6.*	0	Are all animals/birds excluded from the packing, storage, and processing facility?
A7.*	0	Are the storage conditions adequate to maintain product quality and product safety?
A8.*	0	Are the transportation vehicles cleaned and sanitized prior to loading? Are they free from moisture and materials that could contaminate product?
A9.*	0	Does the company have a HACCP/food safety plan in place for this facility? If so, how many critical control points does the plan have?

II. Quality Management Systems

A. Documentation/Control of Records

39.	0	Are quality systems records kept for required amount of time (minimum of three years)?
40.	0	Are procedures implemented to handle review of records?
41.	0	Are records legible, readily retrievable and protected from deterioration?
42.	0	Do company forms include revision date and form number?

B. Quality Assurance/Control Department

43.*	0	Is the Quality Assurance Department adequately staffed to perform product evaluations?
44.	0	Are finished product inspections performed and documented to ensure that the product conforms to specifications?
45.*	0	Are in-process quality checks performed throughout production?
46.	0	Are laboratory facilities sufficient to perform necessary analysis?
47.*	0	Are all records of product evaluations and analysis complete?
48.	0	Are product evaluation records kept throughout the shelf life of the product plus two years? (or three years, whichever is greater)
49.	0	Are reagents labeled and stored according to manufacturer's requirements and recommendations?
50.	0	Is there complete documentation of calibration on equipment? (schedule, procedures and results?)
51.	0	Is calibration certification of scales performed by a licensed agency? (minimum of annually)

III. Personnel

52.*	<input type="checkbox"/>	Do employees wear clean outer garments, gloves, and aprons that are readily washable as appropriate?
53.*	<input type="checkbox"/>	Do employees wear effective hair and beard restraints?
54.*	<input type="checkbox"/>	Are employees free from loose jewelry?
55.*	<input type="checkbox"/>	Are employees working in direct contact with food free from infected lesions or skin diseases? Do employees inform management if they are sick or have been infected with a food borne illness?
56.*	<input type="checkbox"/>	Do employees wash and sanitize hands when entering the processing area? (as applicable)
57.*	<input type="checkbox"/>	Do employees remove protective outer garments prior to leaving the processing area where necessary? (e.g., aprons, lab coats, gloves, etc.)
58.*	<input type="checkbox"/>	Are personal item storage and food consumption in a separate area away from production?
59.1/	<input type="checkbox"/>	<p>Is there regularly scheduled training for new and continuing employees in the following areas?</p> <p><input type="checkbox"/> Hygiene Sanitation:</p> <p><input type="checkbox"/> Good Manufacturing Practices:</p> <p><input type="checkbox"/> Food Safety:</p> <p><input type="checkbox"/> Employee Safety:</p> <p><input type="checkbox"/> Job/Task Performance:</p> <p><input type="checkbox"/> Company Quality Policy and Practices:</p>
60.	<input type="checkbox"/>	Are records kept of all training?
61.	<input type="checkbox"/>	Are signs posted indicating hazardous areas and where protective gear is required?
62.	<input type="checkbox"/>	Is there a Lock out/Tag out program for equipment (including training, instruction, and program implementation)?
63.	<input type="checkbox"/>	Is appropriate safety equipment worn by employees (as designated by the company)?
64.	<input type="checkbox"/>	Are material safety data sheets (MSDS) readily available and properly maintained?

IV. Good Manufacturing Practices

A. Facilities, Equipment and Outside Premises

65.	<input type="radio"/>	Are the outside premises properly surfaced to prevent dust and offensive odors and to promote drainage?
66.	<input type="radio"/>	Are the outside areas maintained in a manner which will prevent rodent and insect harborage?
67.	<input type="radio"/>	Are floors, doors, ceilings, walls and overheads in good repair and designed to facilitate proper sanitation and maintenance?
68.	<input type="radio"/>	Are there back flow prevention devices installed on all water and steam lines?
69.1/	<input type="radio"/>	Condition (Including proper temperatures) of: <input type="radio"/> Ingredient and raw material storage: <input type="radio"/> Cooler/Freezer: <input type="radio"/> Preparation areas: <input type="radio"/> Processing area: <input type="radio"/> Filling area: <input type="radio"/> Finished Product Storage:
70.	<input type="radio"/>	Is there a locked storage area for chemicals, cleaning compounds and similar materials separate from product ingredients and container storage? Are chemicals clearly and properly labeled?
71.	<input type="radio"/>	Is there sufficient lighting to permit efficient operations and cleaning?
72.	<input type="radio"/>	Are buildings reasonably free from excessive dust, heat, steam, condensation, vapors, smoke or fumes?
73.*	<input type="radio"/>	Are product contact surfaces of equipment, containers and utensils made of nonabsorbent corrosion resistant material?
74.	<input type="radio"/>	Is product contact equipment cleanable and in good repair?
75.*	<input type="radio"/>	Are containers and utensils used in handling the product cleaned, stored and utilized in such a manner as to preclude an unsanitary condition?
76.*	<input type="radio"/>	Are motors, conveyor belts and drive mechanisms located and protected so that oil or grease will not contaminate the product?
77.*	<input type="radio"/>	Are catwalks and stiles constructed and located to prevent product contamination?
78.	<input type="radio"/>	Is equipment constructed and located so that product contact surfaces are accessible for cleaning, maintenance and inspection?
79.*	<input type="radio"/>	Are production and preparation areas enclosed?
80.*	<input type="radio"/>	Are doors, windows and other gateways properly protected with screens, air screens or other protective devices?
81.	<input type="radio"/>	Is there a documented maintenance schedule for equipment and facilities?

B. Plant Sanitation

82.*	<input type="checkbox"/>	Is there a formal documented sanitation program?
83.	<input type="checkbox"/>	Name and Title of authorized personnel responsible for sanitation and pre-inspections:
84.	<input type="checkbox"/>	Is all major equipment disassembled for cleaning or can be cleaned-in-place (CIP)?
85.	<input type="checkbox"/>	Are all areas maintained in a clean orderly manner?
86.	<input type="checkbox"/>	Does the documented sanitation program include a master cleaning schedule for all production areas, equipment and facilities? Is it available and implemented?
87.*	<input type="checkbox"/>	Is sanitation of equipment maintained throughout the day to prevent product contamination?
88.	<input type="checkbox"/>	Are routine pre-operation sanitation inspections conducted and documented? Are follow-up procedures documented?
89.1/	<input type="checkbox"/>	Rest room facilities: <input type="checkbox"/> Are they clean, dry and of good general appearance? <input type="checkbox"/> Do they open directly into production area? <input type="checkbox"/> Do they have hot and cold water? <input type="checkbox"/> Do they have sanitizing or antimicrobial soap? <input type="checkbox"/> Do they have signs posted indicating the importance of hand washing (multilingual if appropriate)? <input type="checkbox"/> Do they have independent outside ventilation? <input type="checkbox"/> Do they have clean and accessible waste receptacles? <input type="checkbox"/> Are the restrooms equipped with self-closing doors? <input type="checkbox"/> Are they well lighted?
90.	<input type="checkbox"/>	Is the capacity of the waste storage sufficient?
91.	<input type="checkbox"/>	Is there timely removal of waste?
92.	<input type="checkbox"/>	Is idle equipment stored in an orderly fashion?
93.1/	<input type="checkbox"/>	Do the hand wash and/or hand dip stations have: <input type="checkbox"/> Posted signs (bilingual/multilingual)? <input type="checkbox"/> Sanitizing or antimicrobial soap (Type)? <input type="checkbox"/> Waste receptacles? <input type="checkbox"/> Cold and hot water? <input type="checkbox"/> Controls other than hand operated? <input type="checkbox"/> Appropriate locations? <input type="checkbox"/> Acceptable conditions?

[illegible]

94.*	0	Is facility free from pest infestation? (insect, bird, rodent, etc.)?
95.	0	Is pest control station map properly maintained and available?
96.	0	Are pest control devices properly installed and monitored?
97.*	0	Is routine maintenance and inspection of pest control devices documented?
98.	0	Are the number and placement of pest control/deterrent devices adequate to prevent infestation?
99.	0	Are pest control records maintained for at least three years?
100.	0	Are all pest control chemicals properly identified and separated from potentially hazardous cross-contamination?
101.	0	Is the application of restricted use pesticides conducted or supervised by a licensed pest control operator?

VI. Packaging/Labeling/Warehousing

102.*	0	Are packaging materials clean and stored in dry, clean location?
103.	0	Are visual examinations of packaging completed and documented after closure? (This includes sealing, labeling and coding)
104.	0	Are the packages coded and labeled correctly and legibly? (e.g., does what is in package match the label?)
105.1/	0	Package fill/net weights: 0 Have guidelines been established and is a procedure in place to verify compliance? 0 Are corrective actions taken as needed documented?
106.	0	Are miscoded or mislabeled packages documented and discarded or corrected as appropriate?
107.*	0	Are empty containers protected from contamination?
108.	0	Are there sufficient facilities for handling raw materials and appropriate rotation of materials (first-in, first-out)?
109.*	0	Does raw material storage and handling practices preclude contamination by environmental hazards such as rodents, birds and insects?
110.*	0	Are there temperature-recording devices or a high temperature alarm located in the refrigeration or freezer facilities?
111.	0	Is there a shelf-life sample retention program in place?
112.*	0	Is there appropriate rotation of finished products (first-in, first-out)?
113.	0	Is finished product stored in designated area and separated from raw ingredients?
114.*	0	Is trailer/railcar cleaning and inspection performed and documented prior to loading?

VII. Recall/Return Program

115	0	Is retained product identified and stored in a clearly designated area?
116.*	0	Is a log of Hold product maintained? Are records kept documenting the disposition of Hold product?
117.	0	Is there a person authorized to release product? (Name/Title)
118.*	0	Is there a recall procedure written and tested according to a defined schedule not less than annually?
119.	0	Are returned goods received in a clearly designated area?
120.*	0	Are raw ingredients traceable throughout the process?
121.	0	Is reworked product documented and traceable?
122.*	0	Is there product tracking capability to the customer?
123.	0	Does product tracking system include container code?
124.	0	Is there a system in place and documented to handle customer complaints?

VIII. Food Defense

FDA Food Facility Registration Number Verified: **Yes** **Verified Number**

125.*	0	<u>Management</u> - A Food Defense Plan is established, implemented, and reassessed by management to assure it remains relevant to the operation. No
126.*	0	<u>Management</u> - The Food Defense Plan addresses preventative measures relative to product tampering and deliberate contamination at the processing facility and during transport in commerce.
127.	0	<u>Management</u> - Written security practices list management contacts and procedures for notifying appropriate authorities in the case of an emergency or security issue.
128.*	0	<u>Human Element - Staff</u> - Company personnel hiring practices include screening all potential employees. Photo identification or other measures are employed to restrict access to the facility.
129.*	0	<u>Human Element - Staff</u> - Facility employees have received training in Food Security. The Food Security training is documented.
130.*	0	<u>Human Element - Public</u> - Supplier delivery personnel, contract workers, and visitors are restricted access to vulnerable product areas of the processing and storage facility when not accompanied by a company representative.
131.*	0	<u>Facility</u> - The outside premises are secure with limited access to vulnerable areas. The grounds and facility are monitored for suspicious activity and unauthorized entry. "No Trespassing" signs are visible along the perimeter of the facility, or other measures are being taken to secure and limit access to vulnerable areas.
132.*	0	<u>Operations</u> - Assurances are provided by suppliers of direct or indirect ingredients, product and equipment cleaning and sanitizing compounds, and packaging materials concerning security practices. This may include the use of tamper evident packaging for raw materials, sealing of trailers, and locking of bulk ingredient receiving ports.
133.	0	<u>Operations</u> - The security of water and utilities within the company's control are addressed in the company's plan and define limited access by designated company representatives.

IX. Contract Review: (Complete only if plant packs for Government Contracts)

No points assigned. Answer Yes or No with explanation	
134.	Are procedures documented and implemented to ensure contract terms can and will be met?
135.	Are defined procedures documented and implemented for handling amendments?
136.	Are records of contract reviews and amendments kept?
137.	Is this audit being performed in lieu of a Plant Survey? No If so, what is the corrective action schedule for GMP and Food Defense deficiencies?

Question Scoring:

* = 10 point question

1/ = each part of the question is worth 5 points

All other questions are worth 5 points each.

	10 Point Questions	5 Point Questions
Satisfactory = no points deducted	0	0
Need Improvement = points deducted as follows	5	3
Unsatisfactory = all points are deducted	10	5



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